510(k) SUMMARY   FEB 1 6 2007
as required per 807.92(c)

K061379

1. <u>Submitter's Name and Address:</u>   Draeger Medical Systems, Inc.
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2. <u>Trade Name, Common Name and Classification Name:</u>

A. <u>Trade Name:</u>

Infinity TeleSmart Telemetry System

B. <u>Common Name, Classification Name, Class and Regulation Number:</u>

Common Name	Classification Number	Class	Regulation Number
Detector and Alarm	74DSI	II	21 CFR 870.1025
Monitor, Physiological, Patient (with Arrhythmia Detector or Alarms	74MHX	II	21 CFR 870.1025
Cardiac Monitor	74DRT	II	21 CFR 870.2300
ST Segment Monitor with Alarm	74MLD	II	21 CFR 870.1025
Pulse Oximeter	74DQA	II	21 CFR 870.2700
Pulse Rate Monitor	74BWS	II	21 CFR 870.2300
System, Network and Communication, Physiological Monitors	74MSX	II	21 CFR 870.2300
Radiofrequency Physiological Signal Transmitter and Receiver	74DRG	II	21 CFR 870.2910

3. <u>Predicate Device Identification:</u>

K024108   Infinity MultiView Workstation Telemetry
K051658   Infinity Alpha

4. Device Description:

The INFINITY TeleSmart is a patient-worn transceiver (PWT) that is derived from miniaturization of the INFINITY ALPHA patient monitor. This new device performs telemetry monitoring of ambulatory and non-ambulatory patients, using the same algorithms that are incorporated in the INFINITY ALPHA.

5. Comparison to Predicate Device:

The Infinity TeleSmart Telemetry System is substantially equivalent to the Infinity MultiView Workstation Telemetry cleared for market under 510(k) K024108 and Infinity Alpha, 510(k) K051658.

6. Assessment of non-clinical performance data for equivalence:

Refer to section 10

7. Assessment of clinical performance data for equivalence:

Was not generated for this submission

8 Biocompatibility:

Not applicable

9.Sterilization:

Not applicable

10. Standards and Guidance's:

Refer to section 10